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FROM:

Charles B. Cappellari Gen-Probe Incorporated

Patent Department

10210 Genetic Center Drive San Diego, California 92121 Phone No. (858) 410-8927 Facsimile No. (858) 410-8928 TO: Examiner: Marschel, A.

Group Art Unit 1631

U.S. Patent & Trademark Office Facsimile No. (703) 872-9306

Number of pages (including this cover page): 4

In re Patent Application of:)	Group Art Unit: 1631
McDONOUGH et al.	<u> </u>	Examiner: Marschel, A.
Serial No. 08/480,472)	Confirmation No. 9286
Filed: June 6, 1995) }	Atty. Docket No. GP034-03.DV1
For: NUCLEIC ACID SE AMPLIFICATION	QUENCE)	Date: February 24, 2004

Transmitted herewith is a Request for Reconsideration & Interview Summary.

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence (and any referred to as attached) is being sent by facsimile to 703-872-9306 on the date indicated below to Mail Stop AF, Commissioner for Patents, P.O. Box 1450./Alexandria, VA 22313-1450.

Date: February 24, 2004

Charles B. Cappellari Registration. No. 40,937 Attorney for Applicants

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FEB 2 4 2004 Group Art Unit: 1631 In re Patent Application of: McDONOUGH et al. Examiner: Marschel, A. Atty. Docket No. GP034-03.DV Serial No. 08/480,472

Filed: June 6, 1995 Confirmation No. 9286

NUCLEIC ACID SEQUENCE For: VIA FACSIMILE AMPLIFICATION

REQUEST FOR RECONSIDERATION & INTERVIEW SUMMARY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the Examiner's Final Action mailed on December 29, 2003, Applicants respectfully request reconsideration based on the remarks set forth below. These remarks summarize the substance of a telephone interview between Applicants' representative and the Examiner today.

The rejection of claims 39-41, 67-73, 84, 86, 88-90, 92, 98, 150, 158-162, 168, 173, 176, 180-184, 186, 192-194, 197, 198, 204-213 and 222-226 under 35 U.S.C. § 103(a) as being unpatentable over Boddinghaus et al. (J. Clin. Microbiol. (1990) 28:1751) taken in view of Suzuki et al. (J. Bact. (1988) 170(6):2886) was maintained by the Examiner. Boddinghaus was cited by the Examiner for "generically suggesting and motivating the preparation of probes and/or primers to distinguish microorganisms via sequence differences," and Suzuki was cited for disclosing sequence differences which "in combination with the . . . Boddinghaus et al. motivation and suggestion to make probes and/or primers therefrom results in a series of optional probe and/or primer species." See Final Action at page 3, lines 16-26. Applicants respectfully submit that the Examiner's characterization of the combined teachings of the references is improper because it fails to consider the references in their entirety. See MPEP § 2141.02 at 2100-122 (8th ed., Rev. February 2003).

REQUEST FOR RECONSIDERATION

24-FEB-2004 01:45PM

Serial No. 08/480,472 Atty. Docket No. GP034-03.DV1

Boddinghaus discloses a technique for differentiating between very closely related mycobacterial species based on the amplification and detection of nucleic acid sequences from 16S rRNA. See Boddinghaus at p. 1751, col. 2. Boddinghaus stresses the importance of this technique, as there are a number of mycobacterial species, in addition to M. tuberculosis, that can cause severe lung disease. See Boddinghaus at p. 1751, col. 1. Thus, Boddinghaus teaches the importance of designing primers capable of amplifying regions of nucleic acid that are specific to particular mycobacterial species or to particular members of the genus Mycobacterium. Suzuki, on the other hand, illustrates 16S rRNA sequence differences between M. bovis BCG, E. coli and S. lividans but does not provide any motivation for amplifying and detecting any of the particular regions disclosed for M. bovis BCG. Thus, one skilled in the art reading Boddinghaus and Suzuki for all that they teach would conclude that the 16S rRNA sequences of additional mycobacterial species would be required before any motivation existed for designing probes and primers to the region of Suzuki identified by the Examiner. See also Example 1 of previously cited U.S. Patent No. 5,541,308 (a probe having specificity for M. tuberculosis should be capable of distinghuishing M. tuberculosis over M. intracellulare, as these two organisms have an approximately 98% rRNA homology). Any contrary reading of the references would require improper hindsight reconstruction, as the references provide no motivation whatsoever for distinguishing, by any means, between M. bovis BCG, E. coli and S. lividans. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

Applicants submit that the subject application is in condition for allowance and Notice to the effect is respectfully requested.

No fee is believed due in connection with this Request. If Applicants are mistaken, please charge the amount due to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

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REQUEST FOR RECONSIDERATION

Serial No. 08/480,472 Atty. Docket No. GP034-03.DV1

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Respectfully submitted,

Dated: February 24, 2004

By: Charles B. Cappellary

Registration No. 40,937 Attorney for Applicants

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